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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,782	04/21/2004	S. Michael Owens	D6508	5803

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,782	OWENS ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-7, 9, 10 and 14 are pending.

2. In view of Applicants' Response filed 7/27/06, the following rejections remain.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by the U.S. Pat. No. 6,358,710 B1 (of record), as is evidenced by the specification p. 25 paragraph 2 of the instant application for the reasons set forth in the office action mailed 2/22/06.

The '710 patent teaches a chimeric antibody derived from monoclonal antibody of human and murine origins (col. 7, lines 4-25, in particular).

The '710 patent further teaches the use of human constant regions of IgG2, IgG4 as heavy chain and kappa for light chain, respectively (col. 7, lines 10-15, in particular) and administering the antibody with drugs or clearing agent (i.e. pharmaceutically acceptable carrier, col. 8, lines 46-67, in particular).

As is evidenced in specification p. 25 of the instant application, the leader sequence is to be removed from the polypeptide upon the entry to ER. Thus, the purified antibody after stable transfection will not have the leader sequence.

Applicants' arguments filed on 7/27/06 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on the reference does not teach all the limitations of the claims, as amended. Applicants further argue that the reference does not teach the leader sequences in the chimeric mouse/human monoclonal antibody.

Contrary to the applicants' argument, the '710 patent teaches the chimeric mouse/human monoclonal antibody comprising human constant heavy and light chains and murine variable heavy and light chain region (col. 10, lines 18-27, in particular).

In addition, the '710 patent teaches that the use of signal peptide in expressing the recombinant antibodies in cell culture (col. 23-24 overlapping paragraph, in particular).

The inclusion of leader sequence in claim 1 does not obviate this rejection because the leader sequence is not part of a purified antibody form. As is discussed above, the leader sequence is required for entry to endoplasmic reticulum for secretion from the cell. Thus, the prior art teachings anticipate the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7, 9, 10 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hardin et al. (J. Pharm. Exp. Ther., 285:1113-1122, 1998, of record) as is evidenced by Lim et al. (J. Biol. Chem., 273 (44):28576-28582, 1998, of record) and p. 13-14 of specification of the instant application in view of U.S. Pat. No. 6,358,710 and McLean et al. (Mol. Imm., 37:837-845, 2000, of record) for the reason set forth in the office action mailed 2/22/06.

Applicants' arguments filed on 7/27/06 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on the references or combination of references does not teach the inclusion of leader sequence.

In light of the discussion above and the leader sequence is not being part of the purified form of an antibody, the combination or references does teach the claimed invention.

As discussed in the office action mailed 2/22/06, Hardin et al. teach the murine monoclonal antibody mAb6B5 Fab (abstract, p. 1114 under Materials and Methods, in particular) binds to phencyclidine and the complete sequences of mAb6B5 heavy chain and light chain are disclosed in Lim et al. (Fig.1, in particular).

Hardin et al. do not teach chimeric murine and human antibodies.

It is well known in the antibody therapy art to develop a humanized antibody reduce immunogenicity (the '710 patent, col. 1, lines 35-50).

However, McLean et al. teach various human expression vectors associated with IgG1, IgG2, IgG3, IgG4, and kappa chain constant regions. The expression vectors constructed to include promotor sequences, leader sequence (2.3-2.5, Fig. 1, 2, in particular), drug resistant marker and VDJ cassette. The VDJ cassette can be replaced with any variable region of interest (p. 841, 2.7, in particular). The expression vectors are easy to manipulate to replace various variable regions (i.e. Fab of mAb6B5) to produce functional Ig proteins (p. 843, 3.3, in particular). The expression vectors used in transfection to generate Ig antibodies (2.5, in particular)

As is evidenced in the specification of the instant application, p. 13-14, SEQ ID NO:16 is a chimeric light chain of variable domain of murine antibody and kappa, SEQ ID NO:18 is a chimeric heavy chain of variable domain of murine antibody and IgG2. Human kappa and IgG constant region sequences are well known in the art. Furthermore, the expression vectors taught by McLean et al. includes cDNA encodes constant regions of heavy or light chains, replacing VDJ cassette with known mAb6B5 variable regions results encoding complete SEQ ID NOs: 16 and 18 from SEQ ID NOs: 15 and 17, respectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make chimeric human/murine antibody as taught by the '710 patent and McLean et al. to mAb6B5 Fab taught by Hardin et al.

One of the ordinary skill in the art would have been motivated to combine the variable region of murine mAb6B5 Fab taught by Hardin et al. and Lim et al. in the expression cassette with built-in human constant heavy and light chain regions to produce functional Ig as taught by McLean et al. and to create therapeutically more important chimeric antibody as taught by the '710 patent.

From the teachings of references, one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

7. The following new grounds of rejections are necessitated by the Applicants amendment filed 7/27/06.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7, 9, 10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 9-10 are indefinite in that they are depended upon a canceled claim.

B) Claim 1 currently recites a leader sequence. As is evidenced in specification p. 25 of the instant application, the leader sequence is to be removed from the polypeptide upon the entry to ER. Thus, the leader sequence will not be present in the final purified antibody.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-7, 9, 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the U.S. Pat. No. 6,358,710 B1.

The '710 patent teaches a chimeric antibody derived from monoclonal antibody of human and murine origins (col. 7, lines 4-25).

The '710 patent further teaches the use of human constant regions of IgG2, IgG4 as heavy chain and kappa for light chain, respectively (col. 7, lines 10-15) and administering the antibody with drugs or clearing agent (i.e. pharmaceutically acceptable carrier, col. 8, lines 46-67).

In addition, the '710 patent teaches that the use of a leader sequence (e.g. signal peptide) in expressing the recombinant antibodies in cell culture (col. 23-24 overlapping paragraph, in particular) and expression vectors (col. 22-24, in particular).

Claims 4-7, 9 and 10 are included in this rejection because the claims currently have different scope from the previous claims. The claims 4 and 6 are currently amended to any antibody "has **an** amino acid sequence of SEQ ID NO:16 and SEQ ID NO:18". The claims as currently amended encompass any chimeric antibodies comprising any "portion" of SEQ ID NO:16 or 18 and thus anticipated by any dipeptide or larger peptide. The '710 patent recites use of IgG2 and Kappa constant region which correspond ~ 130th - 462nd amino acid of SEQ ID NO: 18 and 130th and 237th amino acid of SEQ ID NO:16, respectively. Thus, the prior art teachings anticipate the claimed invention.

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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October 4, 2006

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